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## Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Modified) PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98 (b))

ATTY. DOCKET NO.

01722906

SERIAL NO.

09/892,981

APPLICANT

Roland Gerritsen van der Hoop

FILING DATE

June 27, 2001

GROUP

1614

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	TAB	PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
SM	1.	3	1	2	1	0	4	2	02/11/64	Ercoli			
	2.	4	0	8	3	9	7	3	04/11/78	Van der Vies			
	3.	4	4	4	2	0	9	4	04/10/84	Atkinson, et al.			
	4.	4	4	9	6	5	5	6	01/29/85	Orentreich			
	5.	4	5	6	3	4	7	3	01/07/86	Hofman, et al.			
	6.	4	7	8	8	0	6	2	11/29/88	Gale, et al.			
	7.	4	8	6	3	9	7	0	09/05/89	Patel, et al.			
	8.	5	0	2	3	2	5	2	06/11/91	Hseih			
	9.	5	0	2	6	6	9	2	06/25/91	Juno, et al.			
	10.	5	0	5	3	2	2	7	10/01/91	Chiang, et al.			
	11.	5	0	5	9	6	0	3	10/22/91	Rubin			
	12.	5	1	1	6	8	2	8	05/26/92	Miura, et al.			
	13.	5	1	5	2	9	9	7	10/06/92	Ebert, et al.			
	14.	5	2	5	6	6	5	2	10/26/93	El-Rashidy			
	15.	5	3	2	4	5	2	1	06/28/94	Gertner, et al.			
	16.	5	3	3	2	5	7	7	07/26/94	Gertner, et al.			
	17.	5	3	4	0	5	8	4	0/23/94	Spicer, et al.			
	18.	5	3	4	0	5	8	5	08/23/94	Pike, et al.			
	19.	5	3	4	0	5	8	6	08/23/94	Pike, et al.			
	20.	5	3	4	6	9	0	1	09/13/94	Bell, et al.			
	21.	5	3	6	2	4	9	7	11/08/94	Yamada, et al.			
	22.	5	4	6	0	8	2	0	10/24/95	Ebert, et al.			
	23.	5	5	5	0	1	0	7	08/27/96	Labrie			
	24.	5	6	1	0	1	5	0	03/11/97	Labrie			
	25.	5	6	2	9	0	1	9	05/13/97	Lee, et al.			
	26.	5	6	4	8	3	5	0	07/15/97	De Lignieres			
	27.	5	6	6	5	3	7	7	09/09/97	Gonella			
	28.	5	7	3	1	3	0	3	03/24/98	Hsieh			
	29.	5	7	8	0	0	5	0	07/14/98	Jain, et al.			
	30.	5	7	8	3	2	0	8	07/21/97	Venkateshwaran, et al.			
	31.	5	8	0	7	8	4	9	09/15/98	Labrie			
	32.	5	8	4	9	7	2	9	12/15/98	Zoumas, et al.			
	33.	5	8	5	5	9	0	5	01/05/99	Oettel, et al.			

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5/1	34.	5	8	5	5	9	2	0	01/05/99	Chein			
	35.	5	8	8	2	6	7	6	03/16/99	Lee, et al.			
	36.	5	9	0	2	6	0	3	05/11/99	Chen, et al.			
	37.	5	9	0	6	8	3	0	05/25/99	Farinas, et al.			
	38.	6	0	2	4	9	7	4	02/15/00	Li			
	39.	6	0	3	6	9	7	7	03/14/00	Drizen, et al.			
	40.	6	1	1	7	4	4	6	09/12/00	Place			
	41.	6	1	3	9	8	7	3	10/31/00	Hughes, Jr., et al.			
	42.	6	2	2	1	3	7	9	04/24/01	Place			
	43.	6	2	2	5	2	9	9	05/01/01	Golbs, et al.			
	44.	6	2	2	8	8	5	2	05/08/01	Shaak			
	45.	6	2	6	7	9	8	4	07/31/01	Beste, et al.			
	46.	6	3	1	9	9	1	3	11/20/01	Mak, et al.			
47.	6	3	4	2	2	5	0	01/29/02	Masters				
5/1	48.	0	2	0	4	0	6	5	01/10/02	Kanios			
EXAMINER <i>Carlyle</i>									DATE CONSIDERED <i>2/21/03</i>				
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## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

	TAB	DOCUMENT NUMBER	PUB DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANSLATION
SH	49.	9 1 6 7 7 8	01/30/63	UK			
	<del>50.</del>	<del>2 5 1 5 0 4 1</del>	<del>04/29/83</del>	<del>FR</del>			
SH	51.	2 5 1 8 8 7 9	07/01/83	FR w/English Translation			
SH	52.	2 5 1 9 2 5 2	07/08/83	FR w/English Translation			
	<del>53.</del>	<del>2 7 0 5 5 7 2</del>	<del>12/02/94</del>	<del>FR</del>			
	<del>54.</del>	<del>3 2 3 8 9 8 4</del>	<del>10/21/82</del>	<del>DE A1</del>			
SH	55.	9 3 2 5 1 6 8	12/23/93	WO A1			
	56.	9 6 2 0 6 9 9	07/11/96	WO A1			
	57.	9 6 3 6 3 3 9	11/21/96	WO A2			
	58.	9 8 0 6 4 0 4	02/19/98	WO A1			
	59.	0 0 4 0 2 3 0	07/13/00	WO A2			
	60.	0 0 7 4 6 8 4	12/14/00	WO A1			
	61.	0 0 7 6 5 2 2	12/21/00	WO A1			
	62.	0 2 1 1 7 6 8	02/14/02	WO A1			
	63.	0 2 1 7 9 2 6	03/07/02	WO A1			
	64.	0 2 1 7 9 2 7	03/07/02	WO A1			
	65.	0 2 1 7 9 6 7	03/07/02	WO A1			
SH	66.	0 1 9 7 7 5 3	10/15/86	EP A2			
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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

501	67.	Yu, et al., <i>Transdermal Testosterone Administration in Hypogonadal Men: Comparison of Pharmacokinetics at Different Sites of Application and at the First and Fifth Days of Application</i> , <u>Journal of Clinical Pharmacology</u> , Vol. 37, pp. 1129-1138 (1997).
	68.	Yu, et al., <i>Testosterone Pharmacokinetics after Application of an Investigational Transdermal System in Hypogonadal Men</i> , <u>Journal of Clinical Pharmacology</u> , Vol. 37, pp. 1139-1145 (1997).
	69.	<i>Testoderm</i> , Physicians' Desk Reference, Alza 517-520.
	70.	Cunningham, et al., <i>Testosterone Transdermal Delivery System</i> , <u>Pharmacology, Biology, and Clinical Applications of Androgens</u> , Vol. 42, pp. 437-447 (1996 Wiley-Liss, Inc).
	71.	Carey, et al., <i>Transdermal Testosterone Treatment of Hypogonadal Men</i> , <u>The Journal of Urology</u> , Vol. 140, pp. 76-79, (July 1988).
	72.	Bals-Pratsch, et al., <i>Substitution Therapy of Hypogonadal Men with Transdermal Testosterone Over One Year</i> , <u>ACTA Endocrinologica (COPENH)</u> , Vol. 118, pp. 7-13 (1988).
	73.	Meikle, et al., <i>Androderm: A Permeation Enhanced Non-Scrotal Testosterone Transdermal System for the Treatment of Male Hypogonadism</i> , <u>Pharmacology, Biology, and Clinical Applications of Androgens</u> , Vol. 43, pp. 449-457 (1996 Wiley-Liss, Inc.).
	74.	Arver, et al., <i>Long-Term Efficacy and Safety of a Permeation-Enhanced Testosterone Transdermal System in Hypogonadal Men</i> , <u>Clinical Endocrinology</u> , Vol. 47, pp. 727-737 (1997).
	75.	Brocks, et al., <i>Pharmacokinetics of Testosterone in Hypogonadal Men After Transdermal Delivery: Influence of Dose</i> , <u>Journal of Clinical Pharmacology</u> , Vol. 36, pp. 732-739 (1996).
	76.	Cofrancesco, Jr., et al., <i>Transdermal Testosterone Delivery Systems</i> , <u>The Endocrinologist</u> , Vol. 6, No. 3, pp. 207-213 (1996).
	77.	Mazer, et al., <i>Enhanced Transdermal Delivery of Testosterone: A New Physiological Approach for Androgen Replacement in Hypogonadal Men</i> , <u>Journal of Controlled Release</u> , Vol. 19, pp. 347-361 (1992).
501	78.	Schurmeyer, et al., <i>Comparative Pharmacokinetics of Testosterone Enanthate and Testosterone Cyclohexanecarboxylate as Assessed by Serum and Salivary Testosterone Levels in Normal Men</i> , <u>International Journal of Andrology</u> , Vol. 7, pp. 181-187 (1984).
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(37 CFR 1.98 (b))

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

501	79.	Behre, et al., <i>Testosterone Buciclate (20 Aet-1) in Hypogonadal Men: Pharmacokinetics and Pharmacodynamics of the New Long-Acting Androgen Ester</i> , <u>Journal Of Endocrinology And Metabolism</u> , Vol. 75, No. 5, pp. 1204-1210 (1992).
	80.	Jockenhovel, at al., <i>Pharmacokinetics and Pharmacodynamics of Subcutaneous Testosterone Implants in Hypogonadal Men</i> , <u>Clinical Endocrinology</u> , Vol. 45, pp. 61-71 (1996).
	81.	<i>Sexual Dysfunction in the Male – Sexual Arousal Disorder</i> , <u>The Merck Manual</u> , Sixteenth Edition, Ch. 139, pp. 1575-1576 (1992).
	82.	Weinbauer, et al., <i>Pharmacokinetics and Pharmacodynamics of Testosterone Enanthate and Dihydrotestosterone Enanthate in Non-Human Primates</i> , <u>ACTA Endocrinologica (COPENH)</u> , Vol. 122, No. 4, pp. 432-442 (1990).
	83.	Bagatell, et al., <i>Effects of Endogenous Testosterone and Estradiol on Sexual Behavior in Normal Young Men</i> , <u>Journal Of Clinical Endocrinology And Metabolism</u> , Vol. 78, No. 3, pp. 711-716 (1994).
	84.	Bancroft, <i>Endocrinology of Sexual Function</i> , <u>Clinics In Obstetrics And Gynecology</u> , Vol. 7, No. 2, pp. 253-281 (August 1980).
	85.	Damassa, et al., <i>Sex Hormone-Binding Globulin and Male Sexual Development</i> , <u>Neuroscience And Biobehavioral Reviews</u> , Vol. 19, No. 2, pp. 165-175 (1995).
521	86.	Wang, et al., <i>Comparative Pharmacokinetics of Three Doses of Percutaneous Dihydrotestosterone Gel in Healthy Elderly Men – A Clinical Research Center Study</i> , <u>Journal Of Clinical Endocrinology And Metabolism</u> , Vol. 83, No. 8, pp. 2749-2757 (August 1998).
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)	APPLICANT R. Dudley, et al.	
	FILING DATE June 27, 2001	GROUP 1614

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SH	87.	Barrett-Connor, et al., <i>Cognitive Function and Endogenous Sex Hormones in Older Women</i> , <u>J. Am. Geriatr. Soc.</u> , Vol. 47, No. 11, pp.1289-93 (November 1999).
	88.	Javanbakht, et al., <i>Pharmacokinetics of a Novel Testosterone Matrix Transdermal System in Healthy, Premenopausal Women and Women Infected with the Human Immunodeficiency Virus</i> , <u>Journal of Clinical Endocrinology and Metabolism</u> , Vol. 85, No. 7, pp. 2395-2401 (July 2000).
	89.	Shifren, et al, <i>Transdermal Testosterone Treatment in Women with Impaired Sexual Function After Oophorectomy</i> , <u>The New England Journal Of Medicine</u> , Vol. 343, No. 10, pp. 682-688 (September 7, 2000). <b>[Abstract]</b>
	90.	Guzick, et al., <i>Sex, Hormones, and Hysterectomies</i> , <u>The New England Journal Of Medicine</u> , Vol. 343, No. 10, pp. 730-731 (September 7, 2000). <b>[Abstract]</b>
	91.	ENDO 99: <i>Testosterone Patch Effective for Diminished Sexual Function in Surgically Menopausal Women</i> , <u>Doctor's Guide To The Internet</u> , <a href="http://www.docguide.com">http://www.docguide.com</a> (June 15,1999).
	92.	Kuhn, et al., <i>Percutaneous Androgen Treatment for Male Hypogonadism. Compared Efficacy of Testosterone and Dihydrotestosterone: Study of 40 Observations</i> , <u>Endocrinologie</u> , Vol. 14, No. 11, pp. 1031-1036 (1986) (English Translation).
	93.	Wang, et al., <i>Pharmacokinetics of Transdermal Testosterone Gel in Hypogonadal Men: Application of Gel at One Site Versus Four Sites: A General Clinical Research Center Study</i> , <u>The Journal Of Endocrinology And Metabolism</u> , Vol. 85, No. 3, pp. 964-969 (March 2000).
	94.	Marin, et al., <i>Androgen Treatment of Middle-Aged, Obese Men: Effects on Metabolism, Muscle and Adipose Tissues</i> , <u>European Journal of Medicine</u> , Vol. 1, No. 6, pp. 329-336 (October 1992).
	95.	Morley, et al., <i>Androgen Deficiency in Aging Men: Role of Testosterone Replacement Therapy</i> , <u>J. Lab. Clin. Med.</u> , Vol. 135, No. 5, pp. 370-378 (May 2000).
SH	96.	Jaffe, et al., <i>Effect of 5-Alpha-Reductase Inhibition on Sex-Hormone-Binding Globulin in Elderly Men</i> , <u>Horm. Res.</u> , Vol. 41, pp. 215-217 (1994).
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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

821	97.	Sherwin, <i>Affective Changes with Estrogen and Androgen Replacement Therapy in Surgically Menopausal Women</i> , <u>Journal Of Affective Disorders</u> , Vol. 14, pp. 177-187 (1988).
	98.	Sherwin, <i>Estrogen and/or Androgen Replacement Therapy and Cognitive Functioning in Surgically Menopausal Women</i> , <u>Psychoneuroendocrinology</u> , Vol. 13, No. 4, pp. 345-357 (March 1988).
	99.	Sherwin, <i>Sex Hormones and Psychological Functioning in Postmenopausal Women</i> , <u>Experimental Gerontology</u> , Vol. 29, Nos. 3&4, pp. 423-430 (May-August 1994).
	100.	Need, et al., <i>Double-Blind Placebo-Controlled Trial of Treatment of Osteoporosis with the Anabolic Nandrolone Decanoate</i> , <u>Osteoporosis Int.</u> , Supplement 1: S218-222 (1993).
	101.	Raisz, et al., <i>Comparison of the Effects of Estrogen Alone and Estrogen Plus Androgen on Biochemical Markers of Bone Formation and Resorption in Postmenopausal Women</i> , <u>Journal Of Clinical Endocrinology And Metabolism</u> , Vol. 81, No. 1, pp. 37-43 (January 1996).
	102.	Cashdan, <i>Hormones, Sex and Status in Women</i> , <u>Hormones And Behavior</u> , Vol. 29, pp. 354-366 (September 1995).
	103.	Morrison, <i>Androgens in the Elderly: Will Androgen Replacement Therapy Improve Mood, Cognition, and Quality of Life in Aging Men and Women</i> , <u>Psychopharmacology Bulletin</u> , Vol. 33, No. 2, pp. 293-296 (1997).
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	105.	Buckler, et al., <i>The Effects of Low-Dose Testosterone Treatment on Lipid Metabolism, Clotting Factors and Ultrasonographic Ovarian Morphology in Women</i> , <u>Clinical Endocrinology</u> , Vol. 49, pp. 173-178 (1997).
	106.	Douchi, et al., <i>Serum Androgen Levels and Muscle Mass in Women with Polycystic Ovary Syndrome</i> , <u>Obstetrics &amp; Gynecology</u> , Vol. 94, No. 3, pp. 337-340 (1999).
821	107.	Vermeulen, et al., <i>Long-Term Transdermal Dihydrotestosterone Therapy: Effects on Pituitary Gonadal Axis and Plasma Lipoproteins</i> , <u>Maturitas</u> , Vol. 7, pp. 281-287 (1985).
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SH	108.	Davidson, et al., <i>Hormonal Changes and Sexual Function in Aging Men</i> , <u>Journal Of Clinical Endocrinology And Metabolism</u> , Vol. 57, No. 1, pp. 71-77 (1983).
	109.	Basson, <i>Androgen Replacement for Women</i> , <u>Canadian Family Physician</u> , Vol. 45, pp. 2100-2107 (September 1999).
	110.	Persky, et al., <i>The Relation of Plasma Androgen Levels to Sexual Behaviors and Attitudes of Women</i> , <u>Psychosomatic Medicine</u> , Vol. 44, No. 4, pp. 305-319 (September 1982).
	111.	de Lignieres, et al., <i>Treatment of Male Hypogonadism by Topical Administration of Androgens</i> , pp. 273-283 (1980).
	112.	Carlstrom, et al., <i>Relationship Between Serum Testosterone and Sex Hormone-Binding Globulin in Adult Men with Intact or Absent Gonadal Function</i> , <u>International Journal Of Andrology</u> , Vol. 13, pp. 67-73 (1990).
	113.	Ding, et al., <i>Sex Hormone-Binding Globulin Mediates Prostate Androgen Receptor Action via a Novel Signaling Pathway</i> , <u>Endocrinology</u> , Vol. 139, No. 1, pp. 213-218 (January 1998).
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	115.	Nakhla, et al., <i>Stimulation of Prostate Cancer Growth by Androgens and Estrogens Through the Intermediacy of Sex Hormone-Binding Globulin</i> , <u>Endocrinology</u> , Vol. 137, No. 10, pp. 4126-4129 (October 1996).
	116.	Gann, et al., <i>Prospective Study of Sex Hormone Levels and Risk of Prostate Cancer</i> , <u>Journal of National Cancer Institute</u> , Vol. 88, No. 16, pp. 1118-1126 (August 21, 1996). [Abstract]
	117.	Liao, J., <i>Androgen Action: Molecular Mechanism and Medical Application</i> , <u>J. Formos Med. Assoc.</u> , Vol. 93, No. 9, pp. 741-751 (September 1994).
	118.	<i>Testosterone Gel May Help Men with Low Sex Drive</i> , WRAL ONLINE, <a href="http://www.wral-tv.com/features/healthteam/1997/0814-tgel/">http://www.wral-tv.com/features/healthteam/1997/0814-tgel/</a> (August 14, 1997).
SH	119.	Davis, et al., <i>Testosterone Enhances Estradiol's Effects on Postmenopausal Bone Density and Sexuality</i> , <u>Maturitas</u> , Vol. 21, No. 3, pp. 227-36 (April 1995).
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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SH	120.	Schreiner-Engel, et al., <i>Low Sexual Desire in Women: the Role of Reproductive Hormones</i> , <u>Hormones and Behavior</u> , Vol. 23, No. 2, pp. 221-234 (June 1989).
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(37 CFR 1.98 (b))	FILING DATE June 27, 2001	GROUP 1614

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EXAMINER	DATE CONSIDERED 2/21/03	
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